

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

INTERNATIONAL BROTHERHOOD OF
TEAMSTERS LOCAL 456 HEALTH AND
WELFARE TRUST FUND and UFCW LOCAL
1776 AND PARTICIPATING EMPLOYERS
HEALTH AND WELFARE FUND, on behalf of
themselves and all others similarly situated,

Plaintiffs,

-against-

QUEST DIAGNOSTICS INCORPORATED and
NICHOLS INSTITUTE DIAGNOSTICS,

Defendants.

CIVIL ACTION NO: 10-CV-1692

**PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS'
MOTION TO DISMISS AND MOTION TO STRIKE**

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I. PRELIMINARY STATEMENT

This class action arises out of the deceptive, fraudulent and/or otherwise unlawful conduct of Defendants Quest Diagnostics (“Quest”) and Nichols Institute Diagnostics (“NID”)(collectively the “Defendants”) and other third party physicians and firms who worked with Quest and NID in the manufacturing, marketing and/or selling of inaccurate and unreliable medical testing kits to Plaintiffs and the Class. The specific testing kits at issue are the Intact Parathyroid Hormone Kits (“iPTH Kits”), the Bio-Intact Parathyroid Hormone Kits (“Bio-Intact PTH Kits”), the Advantage 25 OH-D Kits (“25 OH-D Kits”), the Advantage ACTH Kits (the “ACTH Kits”) and the Advantage DHEA-S Kits (the “DHEA-S Kits”)(collectively the “Kits”). Plaintiffs allege that Defendants manufactured, marketed and/or sold these Kits in violation of the Racketeer Influenced and Corrupt Organizations Act (“RICO”) as well as the laws of various states.

Defendants have moved to dismiss all causes of action asserted against them and have moved, in a footnote, to strike certain paragraphs of the Plaintiffs’ First Amended Complaint (“Complaint” or “¶”). Plaintiffs oppose all aspects of Defendants’ motion to dismiss and submit that dismissal is not warranted as to any claim against either Defendant. Additionally, Plaintiffs oppose Defendants’ motion to strike on the grounds that Defendants have erroneously applied the law to the allegations in the Complaint. Accordingly, for the reasons set forth below, Defendants’ motions must be denied in their entirety.

II. STATEMENT OF FACTS

At all times relevant to Plaintiffs’ claim, Defendants’ manufactured, marketed and/or sold the Kits as specialty assay kits that would enable laboratories and physicians to perform special

esoteric tests¹ and receive accurate and reliable results. ¶¶ 8, 19, 24, 28, 29, 42, 43, 45, 46, 47, 48, 50, 52, 53, 54, 55, 76, 77, 81, 104, 154, 165, 183, 187, 192. However, unbeknownst to Plaintiff and the Class, these Kits were not providing accurate and reliable results. ¶¶ 7, 8, 44-50, 52-55, 77, 78, 81, 83, 104, 154, 156, 169, 184, 195, 204. Had Plaintiffs and the Class known that the Kits were defective they would not have purchased, reimbursed laboratories and/or otherwise paid for the Kits. ¶¶ 6-10, 51, 56, 62, 68, 82, 86, 89, 98, 101, 105, 151, 161-162, 170, 173, 180, 189, 196, 200, 204, 207.

As early as May 2000, Defendants knew that the results of their Kits were not accurate or reliable. ¶¶ 7-9, 44-50, 52-55, 76-83, 104, 154-156, 160, 165-168, 171, 188, 205. However, rather than inform the public, including the Plaintiff and the Class, of this material information, Defendants, with the help of third parties, discussed *infra* in Section III(D)(1), successfully concealed this information from the Plaintiff, the Class and the general public. *Id.*; *see also* ¶¶ 153, 157-163.

Then, on April 15, 2009, Plaintiffs, the Class and the public were informed that Defendants' Kits had been providing results that were both inaccurate and unreliable. ¶¶ 57-61. Interestingly, this information did not come from Defendants, but from the U.S. government when it announced that civil and criminal actions had been filed under seal against Defendants alleging that Defendants had manufactured, marketed and/or sold the defective Kits to the public with knowledge of their defectiveness as early as May 2000. *Id.* On that date, the following information was made known to the public:

- In 2004 a *qui tam* lawsuit ("the Civil Action") had been filed against Defendants in the Eastern District of New York under the False Claims Act alleging, *inter alia*, that Defendants were defrauding the government by causing healthcare providers to bill

¹ Esoteric testing involves medium to highly complex testing that is usually more costly than other more basic testing such as routine blood testing. The Kits were esoteric testing kits.

Medicare **and** other federal healthcare programs for defective medical test and kits. The Civil Action was filed under seal. ¶ 57.

- Soon thereafter, the U.S. government intervened in the Civil Action and served subpoenas on NID **and** Quest regarding their alleged unlawful conduct. ¶¶ 58-59.
- The Civil Action and subpoenas were influential in the withdrawal of the Kits from the market by Defendants. ¶¶ 57-60.
- The Civil Action and subpoenas were influential in the shutting down of all operations at NID by Quest on or about April 20, 2006. ¶¶ 57-60.
- On or about April 8, 2009, following its investigation, the government filed a criminal action under seal against NID arising out of this same allegedly unlawful conduct (“the Criminal Action”) which was the subject of the Civil Action. ¶¶ 60-61.
- On April 15, 2009, Defendants Quest **and** NID settled the Civil Action whereby they agreed to pay \$262 million dollars to the government plus interest and that NID would plead guilty in the Criminal Action and pay a \$40 million dollar fine. Quest also entered into a non-prosecution agreement with the government. ¶ 61.

Plaintiffs now seek recovery and/or reimbursement of the monies they expended to purchase, reimburse laboratories and/or otherwise pay for the defective Kits. ¶¶ 7, 10, 56, 64, 65, 68, 69, 71, 72, 86, 98, 101, 105, 159, 161, 170, 180, 189, 196, 197, 200, 203, 207.

III. ARGUMENT

A. LEGAL STANDARDS ON DEFENDANTS’ MOTIONS

Defendants bear the burden of proof on a motion to dismiss and/or on a motion to strike. *See Lerner v. Fleet Bank, NA*, 318 F.3d 113, 128 (2d Cir. 2003)(citations omitted); *In Re Prisco*, 2011 WL 9341 at *3 (N.D.N.Y. 2011).

1. Standards for a Motion to Strike

Motions to strike “are generally disfavored, and should not be granted unless it is clear that the allegations have no possible bearing on the subject matter of the litigation.” *Javier H. v. Garcia-Botello*, 239 F.R.D. 342, 350 (W.D.N.Y. 2006); *Lennon v. Seaman*, 63 F.Supp.2d 428, 446-447 (S.D.N.Y. 1999)(citations omitted). The Second Circuit has instructed that motions to

strike made on the basis that the allegation is impertinent and immaterial shall be denied “unless it can be shown that no evidence in support of the allegation would be admissible Thus the courts should not tamper with the pleadings unless there is a strong reason for so doing.” *G-I Holdings, Inc. v. Baron & Budd*, 238 F.Supp.2d 521, 555 (S.D.N.Y. 2002)(quoting *Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 893 (2d Cir. 1976)).

2. Standard for a Rule 12(b)(6) Motion

When deciding a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a district court must determine whether the “[f]actual allegations . . . raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Barkley v. Olympia Mortg. Co.*, 2007 WL 2437810 at *9 (E.D.N.Y. 2007)(quoting *Bell Atl. Corp. v. Twombly*, 127 S.Ct. 1955, 1965 (2007) (internal citations omitted)).² Under the federal pleading standard, a complaint must include a “short and plain statement of the claim showing that the pleader is entitled to relief.” *Barkley*, 2007 WL 2437810 at *9 (quoting Fed. R. Civ. P. 8(a)(2)). A plaintiff must allege “only enough facts to state a claim to relief that is plausible on its face.” *Id.* (quoting *Twombly*, 127 S.Ct. at 1974); *see also Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009).

Under Rule 9(b), a plaintiff “alleging fraud or mistake ... must state with particularity the circumstances constituting fraud or mistake ... [although] [m]alice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). Plaintiffs satisfy

² When deciding a motion to dismiss, a Court may also consider “[d]ocuments that are attached to the complaint or incorporated in it by reference. *Barkley*, 2007 WL 2437810 at *10 (quoting *Roth v. Jennings*, 489 F.3d 499, 503 (2d Cir. 2007). “In addition, even if not attached or incorporated by reference, a document ‘upon which [the complaint] solely relies and which is integral to the complaint’ may be considered by the court in ruling on such a motion.” *Id.* (quoting *Roth*, 489 F.3d at 509). “And whatever documents may properly be considered in connection with the Rule 12(b)(6) motion, the bottom-line principle is that ‘once a claim has been stated adequately, it may be supported by showing any sets of facts consistent with the allegations in the complaint.’” *Roth*, 489 F.3d at 510 (quoting *Twombly*, 127 S.Ct. at 1969).

Rule 9(b) when they “specify the statements they claim were false or misleading and give particulars with respect to the fraudulent statements, including when and where the statements were made and the identity of those responsible for the statements.” *Plumbers and Pipefitters Nat’l Pension Fund v. Transworld Mech., Inc.*, 886 F. Supp. 1134, 1142 (S.D.N.Y. 1995). “Rule 9(b)’s particularity requirement, however, must be read in concert with Rule 8.” *Id.* “In addition, Rule 9’s strictures are relaxed where the alleged fraud concerns facts ‘peculiarly within the opposing party’s knowledge.’” *Id.* A plaintiff is not required to allege in the complaint each specific conversation or representation made in those cases where the very nature of the defendant’s scheme renders such a task impossible at the pleading stage. *See Rothberg v. Chloe Foods Corp.*, 2007 WL 2128376 (E.D.N.Y. 2007)(analyzing RICO claim under relaxed pleading standards where details were only known to defendants); *Zito v. Leasecomm Corp.*, 2004 WL 2211650 at *12 (S.D.N.Y. 2004)(same); *see also Luce v. Edelstein*, 802 F.2d 49, 54 n.1 (2d Cir. 1986); *Burke v. Dowling*, 944 F. Supp. 1036, 1056 (E.D.N.Y. 1995).

B. ALL ALLEGATIONS IN THE COMPLAINT ARE MATERIAL TO THE UNDERLYING CLAIMS AND SHOULD NOT BE STRICKEN

Plaintiffs’ allegations in the Complaint which mention the Civil and Criminal Actions (§§57-62) are material to Plaintiffs’ claims, and evidence of both actions is admissible in Court.

First, all allegations relating to the Criminal Action, including Defendant NID’s guilty plea entered, are properly included in the Complaint, and, as such, “simply do not fall within the purview of Rule 12(f).” *U.S. v. Private Sanitation Indus. Ass’n of Nassau/Suffolk, Inc.*, 793 F. Supp. 1114, 1155 (E.D.N.Y. 1992) (denying motion to strike allegations of criminal charges and pleas because “the inclusion in the complaint of previous criminal charges and of previous criminal pleas [was] clearly offered by the government in order to fill out a factual basis—albeit

a nebulous and largely undifferentiated one—for many of the alleged racketeering acts”).³

Second, the Complaint’s references to the *qui tam* action and findings of the government investigation, all which resulted in criminal and civil prosecution against Defendants Quest and NID are also outside the purview of Rule 12(f). The Complaint references these cases, not to prove the truth of the matters asserted, but to fill out the factual basis for their causes of action.⁴

Lastly, in support of their argument that Plaintiffs’ claims were untimely filed, Defendants reference the Civil and Criminal Actions in an effort to show that Plaintiffs’ were on notice of their unlawful conduct earlier than April 15, 2009. (Def. Br. at 16). It would be unfair and prejudicial for the Court to allow Quest and NID to refer to these Actions, but deny Plaintiffs the same point of reference. Accordingly, Defendants’ motion to strike these allegations must be denied.

C. PLAINTIFFS HAVE SUFFICIENTLY PLED CAUSES OF ACTION AGAINST DEFENDANT QUEST

Defendants challenge the sufficiency of the Complaint as it relates to Quest (Def. Br. at 1-4) and, in support of their challenge, they specifically direct the Court to what they claim is Plaintiffs’ sole allegation against Quest; namely that Quest published misrepresentations related to the defective diagnostic kits in an abstract presented to the Endocrine Society in 2001 (¶ 46). Defendants’ piece-meal review of the Complaint completely ignores all other allegations within the Complaint in which Plaintiffs allege deceptive, fraudulent and/or otherwise unlawful conduct

³ See also *Javier H.*, 239 F.R.D. at 350 (sustaining allegations of criminal conduct and guilty pleas which were related to plaintiffs’ claims and gave factual foundation for plaintiffs’ RICO claims).

⁴ The Complaint’s references to the Civil and Criminal Actions originated from public disclosure documents and news articles which this Court may take judicial notice of when deciding a motion to dismiss. See *Kramer v. Time Warner, Inc.*, 937 F.2d 767, 774 (2d Cir. 1991) (taking judicial notice of contents of corporate filings with SEC); see *DLJ Mort. Capital, Inc. v. Kontogiannis*, 726 F. Supp. 2d 255, 235 (E.D.N.Y. 2010)(sustaining allegations drawn from investigative reports and motion papers filed by government); see also Excerpts from Quest Diagnostics Inc. Form 10-Q for quarter-ended June 30, 2009 annexed hereto as Ex. 1 to the Declaration of Virginia E. Anello.

of both Quest and NID. *See Barkley*, 2007 WL 2437810 at * 12 (sustaining allegations where “read in the context of the pleadings as a whole, the complaint paint[ed] a clear picture”).

Further, Plaintiffs have alleged that at all relevant times, Defendants Quest and NID⁵ were actively involved in the manufacturing, marketing and/or selling of all of the defective Kits and that both Defendants knew or should have known of their defectiveness. ¶¶7-8, 19, 24, 28-29, 42-43, 45-50, 52-55, 76-85, 104, 154-160, 165-168, 171-172, 176-178, 183, 192-195, 205. Plaintiffs have also alleged that both Defendants actively concealed information regarding the defectiveness of the Kits from the Plaintiff, the Class and the public. ¶¶7-9, 44-55, 76-85, 104-105, 154-160, 205.

Additionally, Plaintiffs have alleged that the Civil and Criminal Actions, first disclosed by the U.S. government on April 15, 2009, revealed that Quest, in addition to NID, was a party to the civil action and that formal investigations had been conducted by various governmental agencies against both Quest and NID. ¶¶57-61. Plaintiffs have further alleged that the federal government’s investigation revealed both Defendants acted in concert to unlawfully manufacture, market and/or sell the defective Kits to the public and that investigation prompted

⁵ The relationship between Quest and NID is rather complex given the litany of mergers, acquisitions and name changes that have occurred since both corporations were established. Their relationship is the subject of outstanding discovery propounded on Defendants following a hearing before this Court on December 9, 2010. Thus, Plaintiffs rely upon information published on Quest’s website regarding their relationship. NID, created in 1984, was primarily a manufacturer of diagnostic kits used for esoteric testing. In 1994, NID was purchased by Metropolitan Pathology (“MedPath”). *See* http://www.questdiagnostics.com/brand/company/b_comp_history.html. MetPath, as of 1982, had been purchased by Corning Incorporated, so when it purchased NID in 1994, it was in essence purchasing NID for Corning Incorporated. *Id.* MetPath’s name was officially changed to Corning Clinical Labs in 1995. *Id.* In 1996 Corning Incorporated spun off its laboratory testing business, inclusive of Corning Clinical Labs and NID, and established Quest. *Id.* Corning Incorporated’s spin-off of Quest was pursuant to a transaction agreement which provided for “assumptions of liabilities and cross-indemnities designed to allocate ...financial responsibility for the liabilities arising out of or in connection with ... the clinical laboratory business to Quest Diagnostics and its subsidiaries....” *See* Quest Form 10-12B/A filed with the SEC on Nov. 26, 1996, annexed as Ex. 2 to the Declaration of Virginia E. Anello.

the filing of the Criminal Action. ¶¶58-61.⁶

Accordingly, the Complaint contains sufficient allegations to provide Defendant Quest with “fair notice of ... [plaintiffs’] claim[s] and the grounds upon which [they] rest[],” and Defendants’ motion to dismiss all causes of action against Defendant Quest must be denied. *See Twombly*, 127 S.Ct. at 1965-1966.

D. PLAINTIFFS HAVE STATED A VIABLE CLAIM FOR VIOLATION OF RICO

1. Plaintiffs Have Alleged a “Defective Kit Enterprise” as an Association-In-Fact Enterprise Distinct from Defendants Quest and NID

Plaintiffs claim that Defendants violated RICO § 1962(c) which provides that “[i]t shall be unlawful for any person employed by or associated with any enterprise ...to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity.” ¶¶74-90. To support their claim, Plaintiffs have alleged that Quest and NID were separate persons that unlawfully conducted the affairs of the distinct “Defective Kit Enterprise,” an association-in-fact enterprise comprised of Quest, NID and other third parties,⁷ the goal of which was to suppress data that showed the Kits were producing inaccurate and unreliable results. ¶¶7-9, 19, 23,44-50, 52-55, 57, 60, 75-85.⁸

⁶ Contrary to Defendants’ arguments (Def. Br. at 4), Quest’s liability is not merely limited to a theory of “successor liability.” Indeed, the issue of Quest’s liability, contractual or otherwise, for the conduct or acts of NID, is the subject of outstanding discovery propounded on Defendants following a hearing before this Court on December 9, 2010. Following the completion of discovery on this issue a determination can be made as to the successor liability of Quest. However, at this stage, the Complaint alleges enough facts against Quest so as to survive a motion to dismiss pursuant to Rule 12(b)(6).

⁷ As discussed in more detail below, the other third parties include those marketing firms, physicians, scientists, public relations firms and/or other consultants, independent from Quest or NID, who worked with Quest and NID to conduct the unlawful affairs of the Defective Kits Enterprise.

⁸ Plaintiffs have also alleged, *inter alia*, that the Defective Kits Enterprise “acted to enable [NID] to fraudulently manufacture, market and promote defective [] Kits as accurate and reliable” (¶ 76); that the Defective Kits Enterprise “was calculated to ensure that the defective [] Kits were utilized in great quantities by physicians and laboratories, despite knowing they were inaccurate and unreliable and actively suppressing information questioning the devices’ accuracy and reliability” (¶ 83); and that the conduct of the Deceptive Kits Enterprise “amounted to a common course of conduct intended to deceive and harm, physicians, laboratories, the public, Plaintiffs and the

Defendants' argue that Plaintiffs' § 1962(c) claim should be dismissed because they "have been wholly unable to allege a RICO enterprise that is distinct from the defendant RICO persons." (Def. Br. at 5-9). While Plaintiffs' acknowledge that it is well-settled law that an enterprise and person under § 1962(c) must be distinct, *Cedric Kushner Promotions Ltd. v. King*, 121 S.Ct. 2087, 2090 (2001), Plaintiffs submit that Defendants have misapplied this law to the facts of this case.

The U.S. Supreme Court has held that a defendant person may be a member of an association-in-fact enterprise, so long as the person is not the sole member. *Id.* Thus, separate and legally distinct persons, such as Quest and NID, can be held liable under § 1962(c) even if they are also members of the enterprise. *Id.*; see also *Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 263 (2d Cir. 1995)(holding that sibling corporations were separate RICO persons engaged in an association-in-fact enterprise despite their sharing common ownership, common officer and common agents and thus, could not escape § 1962(c) liability by claiming to be one single entity); see also *Cullen v. Margiotta*, 811 F.2d 698, 729 (2d Cir. 1987), *overruled on other grounds*, *Agency Holding Corp. v. Malley-Duff & Associates, Inc.*, 107 S.Ct. 2759 (1987)("While we have held that a solitary entity cannot, as a matter of law, simultaneously constitute both the RICO 'person' whose conduct is prohibited and the entire RICO 'enterprise' whose affairs are impacted by the RICO person, [citations omitted], we see no reason why a single entity could not be both the RICO 'person' and one of a number of members of the RICO 'enterprise.'").⁹

Class" (§ 85).

⁹ See also *In re Lupron Mktg. and Sales Practices Litig.*, 295 F. Supp. 2d 148, 172-73 (D. Mass. 2003)(sustaining third party payors claims against two distinct companies, a Japanese drug manufacturer and its U.S. associate, because "a defendant may be both a person and a member of a collective RICO enterprise."); see also *U.S. v. Goldin Ind., Inc.*, 219 F.3d 1271, 1276-1277 (11th Cir. 2000)(RICO liability may stand when "separate and distinct

Defendants' reliance on *Discon, Inc. v. NYNEX Corp.*, 93 F.3d 1055 (2d Cir. 1996), *rvsd. on other grounds*, *NYNEX Corp. v. Discon, Inc.*, 119 S.Ct. 493 (1998), *Riverwoods Chappaqua Corp. v. Marine Midland Bank*, 30 F.3d 339 (2d Cir. 1994), and *Rush v. Oppenheimer & Co.*, 628 F.Supp. 1188 (S.D.N.Y. 1999), for the proposition that Plaintiffs failed to establish the existence of an enterprise (Def. Br. at 5-8), is misplaced because the Defendant persons in those cases were not acting on behalf of an enterprise but were "acting within the scope of a single corporate structure, guided by a single corporate consciousness."¹⁰ See *Discon*, 93 F.3d at 1064. Here, in contrast, Quest and NID are legally separate entities that can be differentiated from the enterprise group, consisting of Quest, NID and other third parties. ¶¶19, 23, 57, 60, 75-85. Thus, because Quest and NID are distinct from the Defective Kits Enterprise, Plaintiffs have asserted a viable RICO claim.

Defendants have further argued that Plaintiffs' allegations of "corporate agents" do not raise a distinction between the RICO enterprise and the RICO person. (Def. Br. at 8). First of all, Defendants argument fails because, as discussed above, a distinction between the Deceptive Kits Enterprise and Quest and NID would exist regardless of whether Plaintiffs had alleged that other third parties were involved in the enterprise.

Second, Defendants argument fails because Plaintiffs have not alleged that these third parties were the "corporate agents" of Quest and/or NID. See ¶¶ 76-78. Rather, Plaintiffs have included these third parties within the Complaint as part of the Deceptive Kits Enterprise because these independent third parties, inclusive of marketing firms, physicians, scientists, public

corporation(s)) are also "distinct from the association consisting of the union of . . . (the) corporations which comprises the enterprise.").

¹⁰ Indeed, in *Discon*, the Second Circuit specifically acknowledged that its holding did not apply to cases such as this one, in which it is alleged that legally separate entities are involved in carrying out the affairs of an enterprise and the entities can be differentiated from the enterprise group. *Discon*, 93 F.3d at 1063-1064; see also *Securitron*, 65 F.3d at 263.

relations firms and other consultants, acted in concert with Quest and NID to conceal and suppress information regarding the accuracy and reliability of the Kits. *Id.*; see e.g. *In re Lupron*, 295 F.Supp.2d at 160-162. While Plaintiffs may have used the terms “agents” within the Complaint, Plaintiffs’ intent was to use it in its broadest sense to include those marketing firms, physicians, scientists, public relations firms and other third parties or consultants. *Id.*

In this regard, Plaintiffs have appropriately included these third parties as part of the Deceptive Kits Enterprise. See, e.g., *In re Neurontin Marketing, Sales Practices and Prod. Liability Lit.*, 433 F.Supp.2d 172, 183 (D. Mass. 2006)(denying motion to dismiss where enterprise consisted of Pfizer and “medical marketing firms named in the complaint” to which Pfizer had “systematic linkages,” “regular communication,” “financial ties” and “continued interaction with a common purpose” to promote Neurontin for off-label uses); see also *In re Actiq Sales and Marketing Practices Lit.*, No. 07-cv-4492, at *5-6 (E.D. Penn. 2009)¹¹(finding that the manufacturer of the allegedly defective product could serve as both the RICO enterprise and the RICO person where the third party payor plaintiffs were able to name the marketing firms, physicians, Ph.D.s and public relations firms and other third parties or consultants who had, along with the manufacturer, conducted an enterprise meant to fraudulently manufacture, market and/or sell the defective products.); *In Re Zyprexa Litig.*, 493 F.Supp.2d 571, 576 (E.D.N.Y. 2007), *vacated on other grounds*, 620 F.3d 121 (2d Cir. 2010)(denying motion for summary judgment where Plaintiffs alleged an enterprise consisting of Eli Lilly and other third parties, including marketing firms and physicians).¹²

¹¹ Plaintiffs’ have annexed the Court’s decision in *In re Actiq* as Ex. 3 to the Declaration of Virginia E. Anello.

¹² Of course, the plaintiffs in *In re Neurontin*, *In re Actiq* and *In Re Zyprexa* were able to allege the identities of these third parties because some discovery had taken place prior to the filing of the operative complaint. Here, on the other hand, because the Civil Action is still under seal Plaintiffs have little to no information regarding these third parties. In this regard, the identity of these third parties is the subject of outstanding discovery propounded on Defendants following a hearing before this Court on December 9, 2010.

As such, Defendants' motion should be denied.

2. Plaintiffs Have Pled The "Defective Kit Enterprise" and The Racketeering Activity Underlying the Enterprise with Particularity under Rule 9(b)

As set forth above, Plaintiffs have alleged specific facts in support of their RICO action against the Defendants – facts which originated from the public record and the U.S. government's announcement on April 15, 2009 of the limited details underlying the sealed Civil and Criminal Actions that had been filed against *both* Defendants. *See* ¶¶7-9, 19, 23, 28-29, 41-50, 52-55, 57-61, 75-85.¹³

It is well-established that where a complaint asserts claims of fraud arising out of an underlying scheme to defraud and/or deceive the public, a description of the underlying scheme and its connection to the fraud being alleged will survive a motion to dismiss. *See Republic of Columbia v. Diageo North America, Inc.*, 531 F. Supp.2d 365, 442 (E.D.N.Y. 2007) (citing *Neder v. United States*, 119 S.Ct. 1827, 1840 (1999)); *see also In re Sumitomo Copper Litig.*, 995 F. Supp. 451, 456 (S.D.N.Y. 1998); *Giuliano v. Everything Yogurt, Inc.*, 819 F. Supp. 240, 244 (E.D.N.Y. 1993) ("the complaint need not specify the time, place and content of each mail communication where the nature and mechanics of the underlying scheme is sufficiently detailed, and it is enough to plead the general content of the misrepresentation without stating the exact words used..., especially when the information is in possession of the defendants.").¹⁴ Any additional facts which Defendants argue Plaintiffs should have alleged in the Complaint are completely within Defendants' own knowledge. *See Plumbers*, 886 F. Supp at 1142.

Here, the Complaint describes in sufficient detail Defendants' racketeering activities to

¹³ Defendants have also argued that Plaintiffs failed to plead with particularity as to Defendant Quest. This argument was addressed *supra* in section III(C).

¹⁴ *Cf. Center Cadillac v. Bank Leumi Trust Co.*, 808 F. Supp. 213, 229 (S.D.N.Y.1992)(finding the particularity requirement met where complaint detailed nature and mechanics of fraud because plaintiffs were not required to plead exact time, place and content of each mail communication).

survive a motion to dismiss. Plaintiffs allege: (1) that as early as May 2000 Defendants became aware that their Kits were producing results that were not accurate and/or reliable and that they failed to inform the Plaintiffs and other members of the Class of this information, (¶¶7-9, 44-50, 52-55, 76-83, 104, 153-163, 160, 165-168, 171, 188, 205); (2) that Defendants continued to misrepresent on the labels and in their marketing materials for these deceptive Kits that they would provide accurate and reliable results (¶¶7-9, 42-50, 77, 81, 104, 154-156, 165-169, 176-179, 183-184, 192-195); (3) regarding the iPTH Kit, that Defendants' continued to market the products on its label as producing IRMA equivalent results and continued to distribute marketing materials describing the iPTH Kit as having "excellent correlation" to the IRMA kit, (¶¶42-43, 44-50); and (4) that the Defective Kits Enterprise "was a deliberate effort to use (two) independent (companies) to give a spurious validity," to the fraudulent accuracy claims in regard to the tests (¶¶76-78, 81, 84-85 81). *See Securitron*, 65 F.3d at 264,

Thus, the Complaint contains sufficiently detailed information which provided Defendants with a fair notice of the RICO claims against them, and, as such, Defendants' motion to dismiss Plaintiffs' RICO claims should be denied.

3. Plaintiffs' Complaint Adequately States a Claim Under RICO § 1962(d).

Defendants argue that the Complaint fails to plead a conspiracy under RICO § 1962(d). (Def. Br. at 11).¹⁵ Here, Plaintiffs allege (1) the existence of the Defective Kits Enterprise, an association-in-fact enterprise affecting interstate commerce, (¶¶7-9, 19, 23, 44-50, 52-55, 57, 60, 70, 75-85, 93); (2) that Defendants Quest and NID knowingly joined the conspiracy to

¹⁵ Pursuant to 18 U.S.C. § 1962(d), it is "unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section." To plead a RICO conspiracy under section 1962(d), a complaint must allege: "(1) the existence of enterprise affecting interstate commerce, (2) that the defendant knowingly joined the conspiracy to participate in the conduct of the affairs of the enterprise, (3) that the defendant participated in the conduct of the affairs of the enterprise, and (4) that the defendant did so through a pattern of racketeering activity by agreeing to commit, or in fact committing, two or more predicate offenses." *In re Lupron*, 295 F. Supp. 2d at 176.

participate in the conduct of the affairs of the enterprise, (*Id.*; *see also* ¶¶58-61, 94-98); (3) that Defendants Quest and NID participated in the conduct of the affairs of the enterprise by, among other acts, publishing in conjunction with NID's abstracts suppressing information and misrepresenting the accuracy of the Defective Kits, and reached an agreement with the U.S. government in regard to activities similar to those alleged to have occurred in furtherance of the Defective Kits Enterprise (*Id.*); and (4) that Defendants Quest and NID did so through a pattern of racketeering activity by agreeing to commit, or in fact committing, two or more predicate offenses (*Id.*). In addition, Plaintiffs' allegations also specify the dates, origin, destination and content of the fraudulent statements Defendants conspired to disseminate and did disseminate by means of interstate mail and wire communications. (¶¶ 45-46, 52-55, 59-61, 70, 76-85). Thus, a claim under 1962(d) exists and has been properly plead.

E. Plaintiffs Have Stated Viable Causes of Action for Violations of the State and Common Law of Various State Jurisdictions

1. Defendants' Erroneously Applied Only New York Law to Plaintiffs' State and Common Law Causes of Action

By limiting their analysis to New York law, Defendants have presumed that Plaintiffs do not have Article III standing to sue for violations of laws other than the state of New York and/or that the Court will ultimately decide to apply New York law to Plaintiffs' state and common law claims. (*See e.g.* Def. Br. at 22). Simply put, Defendants' presumptions are wrong.

At the pleading stage, the only appropriate inquiry regarding Article III standing is whether the plaintiffs have standing to bring suit on their own behalf. *See In Re Bayer Corp. Combination Aspirin Lit.*, 701 F.Supp 2d. 356, 377 (E.D.N.Y. 2010)(finding named plaintiffs can bring suit under the laws of various jurisdictions in which they are not residents so long as they have standing to bring suit on their own behalf); *see also Ramirez v. Dollar Phone Corp.*, 2009

WL 3171738 at *9 (E.D.N.Y. 2009)(holding that “...individual standing to allege violations of consumer protection laws in states other than those in which they purchased Defendants’ [product] is immaterial’ on a motion to dismiss a class action.”)(quoting *Ramirez v. STI Prepaid LLC*, 644 F. Supp.2d 496, 505 (D.N.J. 2009)).¹⁶ Thus, because Defendants do not dispute that Plaintiffs have standing to bring suit on their own behalf,¹⁷ Defendants erred in their analysis of Plaintiffs’ state law claims by limiting their analysis to solely New York law. As such, their motion to dismiss Plaintiffs’ state law claims must be denied.

Similarly, Defendants’ failure to appreciate choice-of-law determinations that this Court will ultimately need to make warrants the denial of their dismissal motion. It is premature at the dismissal stage for the Court to “narrow the scope of state laws pursuant to which plaintiffs could pursue their claims.” See *In Re Bayer Corp. Combination Aspirin Litig.*, 701 F.Supp.2d at 378 (deferring choice-of-law decision until class certification stage); see also *Whitson v. Bumbo*, 2008 WL 2080855 (N.D.Cal. 2008)(finding variations in state law immaterial to Rule 12(b)(6) analysis and are best to be addressed at class certification stage); *Labajo v. Best Buy Stores*, 478 F. Supp.2d 523, 529 (S.D.N.Y. 2007)(finding that choice-of-law analysis is more appropriate at class certification stage). By applying only New York law to their dismissal motion, Defendants’ prematurely and inappropriately narrowed the scope of Plaintiffs’ state and common

¹⁶ Further, any concern Defendants may have regarding the fact that Plaintiffs are not residents of all jurisdictions in which they allege violations of law, is a matter best left to be brought to the Court’s attention at the class certification stage, at which point the Court will determine the adequacy of the class representatives. See *In Re Bayer Corp. Combination Aspirin Lit.*, 701 F.Supp.2d at 376 (finding that defendants’ lack of standing argument was flawed because it “confuse[d] Article III standing with the adequacy of named plaintiffs in a class action.”); see also *In re Grand Theft Auto Video Game Consumer Litig.*, 2006 WL 3039993, at *3 (S.D.N.Y. 2006)(deferring the standing issue, where the standing of the named representatives are not in dispute, until the class certification stage at which time the Court will look to “whether the named Plaintiffs injuries are sufficiently similar to those of the purported Class...”)(citing *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 377 (S.D.N.Y. 2002)); *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 504-505 (S.D.N.Y. 1996)(“[t]he question of standing is separate and distinct from the question of plaintiff’s right to represent a purported class under Rule 23”).

¹⁷ Defendants originally made such an argument in their October 10, 2010 letter to the Court, but following a pre-motion conference held before the Court on December 9, 2010 at which the Court stated that it did not think there was a “serious standing issue,” Defendants appear to have abandoned this argument. See *Dec. 9, 2010 Tr.* at p.4.

laws claims. In this regard, their motion to dismiss must be denied.

2. Plaintiffs' Have Stated Viable State and Common Law Causes of Action

Regardless of which jurisdictions' law this Court ultimately decides to apply, Plaintiffs have adequately pled their claims for relief to survive a Rule 12(b)(6) motion. For purposes of this motion, the Court can apply the law of New York and Pennsylvania, the states of residence of the Plaintiffs, and the law of California and New Jersey, the states of residence of Defendants.

a. Plaintiffs' Have Stated a Valid Claim for Relief under the Consumer Protection Statutes of Various Jurisdictions¹⁸

Plaintiffs have alleged that they sustained a direct injury resulting from Defendants' unlawful conduct by purchasing, reimbursing laboratories and/or otherwise paying for the cost of the defective Kits. (¶¶ 7, 10, 64, 65, 68, 6971, 72, 86, 98, 101, 105, 159, 170, 180, 189, 200, 203, 207.) These injuries are direct injuries recognized as such under the consumer protection statutes of New York and other jurisdictions throughout the country. *See e.g., In Re Zyprexa Litig.*, 493 F.Supp.2d at 576 (E.D.N.Y. 2007)(finding that third party payor has standing under New York law to assert claim for direct injuries resulting from amounts overpaid as result of illegal or deceptive marketing practices); *Desiano v. Warner-Lambert Company*, 326 F.3d 339, 350 (2d Cir. 2003)(same applying New Jersey law); *In re Bextra and Celebrex Marketing, Sales Practices and Prod. Liab. Litig.*, 2007 WL 2028408 at *5 (N.D. Cal. 2007)(same applying California law); *Prohias v. Pfizer, Inc.*, 490 F.Supp.2d 1228, 1238-1239 (S.D. Fla. 2007)(finding third party payor sufficiently pled action under Pennsylvania law against manufacturer for

¹⁸ The liberal standard under Fed. R. of Civ. P. 8(a) applies to claims for violation of consumer protection statutes and unjust enrichment. *See, e.g., Pelman v. McDonald's Corp.*, 396 F.3d 508, 511 (2d Cir. 2005)(“an action under § 349 [of the New York General Business Law] is not subject to the pleading-with-particularity requirements of rule 9(b), Fed. R. Civ. P., but need only meet the bare-bones notice-pleading requirements of rule 8(a), Fed. R. Civ. P.”). Indeed, *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513 (2002), “sounded the death knell for the imposition of a heightened pleading standard except in cases in which either a federal statute or specific Civil Rule requires that result.” *Lawson v. Affirmative Equities Co., L.P.*, 341 F. Supp. 2d 51, 67 n.25 (D.Mass 2004)(quoting *Educadores Puertorriqueños en Acción v. Hernández*, 367 F.3d 61, 66 (1st Cir. 2004)).

concealing information about product's safety which caused it to overpay for product). Thus, Defendants' attempt to re-characterize Plaintiffs' injuries as indirect or derivative, without further explanation, solely because New York does not allow third parties to bring actions for indirect or derivative injuries (Def. Br. at 21.) is incredible.¹⁹

In addition to alleging a direct injury, Plaintiffs allege misconduct on the part of the Defendants that was consumer-oriented. ¶¶ 9, 62, 70, 81-82 104-105. Yet, even if Plaintiff had not made such allegations, not all jurisdictions, including New York, require that the conduct complained of be consumer-oriented, so long as some harm to the public may result. *See Securitron*, 65 F.3d at 264 (holding that while New York's statute "is, at its core, a consumer protection statute" others may "have standing to bring a claim under this [statute]... so long as some harm to the public at large is at issue."); *Blakemore v. Superior Court*, 129 Cal. App. 4th 36, 49 (2d Dist. 2005)(finding that act or practice is fraudulent under California's Unfair Competition Law if members of the public are likely to be deceived); *Int'l Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc.*, 2004 WL 3767338 at *4 (N.J. Sup. 2004)(finding that New Jersey legislature's intentional use of word "person" as opposed to "consumer" revealed that it intended the scope of New Jersey's consumer fraud act to cover business entities, such as third party payors); *Prohias*, 490 F. Supp. 2d at 1238-1239 (finding third party payor sufficiently alleged claim against manufacturer under Pennsylvania's Unfair Trade Practices and Consumer Protection Laws).

Here, because Plaintiffs have alleged a direct injury as a result of Defendant's unlawful conduct (¶¶ 7, 10, 64, 65, 68, 69, 71, 72, 86, 98, 101, 105, 159, 170, 180, 189, 200, 203, 207) and

¹⁹ Though additional healthcare costs were incurred by Plaintiffs because of Defendants' defective Kits, Plaintiffs are not seeking a refund or reimbursement of these indirect costs and Plaintiffs' complaint does not contain such allegations. Thus, Defendants' reliance upon *Blue Cross and Blue Shield of New Jersey, Inc. v. Philip Morris USA Incorporated*, 818 N.E.2d 1140 (N.Y. 2004), is misplaced.

because Plaintiffs have alleged unlawful conduct directed at “consumers” and the public at large so as to state a claim under the consumer protection statutes of various districts throughout the country (¶¶ 9, 62, 70, 81-82, 85, 104-105, 154, 156, 157, 159-161, 165, 168, 176, 179, 187), Plaintiffs have stated a viable cause of action. Accordingly, Defendants’ motion must be denied.

b. Plaintiffs’ Have Pled Reliance so as to State a Claim for Fraud and/or Misrepresentation

Defendants seek dismissal of Plaintiffs’ claims of fraudulent misrepresentation, fraudulent concealment and negligent misrepresentation on the grounds that Plaintiffs failed to provide “*proof*” of reliance, a necessary element of all three causes of action.²⁰ (Def. Br. at 22).

However, all that is necessary at the motion to dismiss stage is that Plaintiffs have pled reliance in their complaint. *See Scot v. J. Anthony Cambece Law Office, P.C.*, 600 F.Supp.2d 479, 483 (E.D.N.Y. 2009)(the Court’s role in ruling on Rule 12(b)(6) motion “is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof.” (quoting *Ryder Energy Dist. Corp. v. Merrill Lynch Commodities, Inc.*, 748 F.2d 774, 779 (2d. Cir. 1984)). Here, the Complaint is replete with allegations that Plaintiffs relied upon Defendants’ unlawful behavior (¶¶ 56, 71, 161, 170, 180, 196, 197) and that said reliance caused them to purchase, reimburse laboratories and/or otherwise pay for the cost of the defective Kits. (*Id.*; *see also* ¶¶ 7, 10, 64, 65, 68, 69, 71, 72, 86, 98, 101, 105, 159, 170, 180, 189, 200, 203, 207.) Accordingly, Defendants’ motion must be denied.

c. Plaintiffs’ Payment for the Defective Kits Gives Rise to Claims for Breach of Express and Implied Warranties and Unjust Enrichment

Defendants’ arguments that Plaintiffs have failed to state a claim for which relief can be granted as to breach of express and implied warranties (Def. Br. at 23) and as to unjust

²⁰ Because Defendants have focused solely on the reliance element of these claims to argue that Plaintiffs have failed to state a claim for which relief can be granted, Plaintiffs limit their discussion to the issue of reliance.

enrichment (Def. Br. at 23-24), rest solely upon their mistaken position that Plaintiffs did not purchase, reimburse laboratories and/or otherwise pay money for the allegedly defective Kits. Once again, Defendants' arguments ignore the specific allegations in the Complaint that Plaintiffs purchased, reimbursed laboratories and/or otherwise paid for the cost of the defective Kits, and as a result they were damaged economically. ¶¶ 7, 10, 64-65, 68-69, 71-72, 86, 98, 101, 105, 159, 170, 180, 189, 200, 203, 207.

Moreover, Plaintiffs need not have directly purchased the defective kits from Defendants since most states have eliminated vertical privity as a requirement for these types of claims. *See Spring Motors Dist., Inc. v. Ford Motor Co.*, 489 A.2d 660 (N.J. 1985)(eliminating vertical privity under New Jersey warranty law); *Goodman v. PPG Indus., Inc.*, 849 A.2d 1239, 1235 (Penn. Sup. 2004)(confirming that party bringing breach of warranty action need not be party that purchased allegedly defective product from manufacturer); *Bridge Street Commons LLC v. Superior Court*, 2004 WL 1535616 at *5 (Cal. App. 3d Dist. 2004)(finding that privity is not required in breach of express warranty action where purchaser relied upon manufacturer's labels or packaging materials); *Shuldman v. Daimler Chrysler Corp.*, 768 N.Y.2d 214, 216 (2d Dept. 2003)(discussing New York's lack of privity requirement in breach of express warranty claims under Uniform Commercial Code); *Sperry v. Crompton Corp.*, 863 N.E.2d 1012, 1018 (N.Y. 2007)(finding privity is not required under New York unjust enrichment law); *County of San Bernardino v. Walsh*, 69 Cal. Rptr. 3d 848, 856 (Cal. App. 2 Dist. 2007); *First State Orthopedics v. Concentra, Inc.*, 534 F. Supp. 2d 500, 518 (E.D. Pa 2007).²¹

²¹ Indeed, most states allow third parties to reach through the chain of distribution to the manufacturer for express and implied warranty claims. *Alloway v. General Marine Indus., L.P.*, 695 A.2d 264, 275 (N.J. 1997); *see also Kinetic Co. v. Medtronic, Inc.*, 672 F.Supp.2d at 933, 947 (D.Minn. 2009)(finding that third party payor could bring action for breach of express and implied warranties against manufacturer of defective product where there was clear connection between third party payor that had reimbursed original purchaser for product). Similarly, for unjust enrichment claims, all that is generally required is a relationship between plaintiff and defendant that is not too attenuated. *Sperry*, 863 N.E.2d 1012; *cf. County of San Bernardino*, 69 Cal.Rptr.3d at 856 (holding that plaintiff

Accordingly, Plaintiffs have asserted valid causes of action against Defendants for breach of express warranty, breach of implied warranty and unjust enrichment and, thus, Defendants' motion to dismiss these claims must be denied.

F. PLAINTIFFS' CAUSES OF ACTION WERE TIMELY COMMENCED

Plaintiffs' causes of action did not accrue and/or were equitably tolled until April 15, 2009, when Defendants' unlawful conduct was first publicized by the federal government's announcement of the Civil and Criminal Actions. This was when Plaintiffs first learned they had been economically injured. Plaintiffs commenced this action on April 15, 2010 – one year from the date of the government's announcement. Given that all of Plaintiffs' claims have a statute of limitations period greater than one year, all of Plaintiffs' claims were timely filed.²²

Defendants argue that most of Plaintiffs' causes of actions were untimely filed because Plaintiffs should have been on inquiry notice of Plaintiffs' claims as early as 2005 and they rely upon outside pleadings, such as product withdrawal notices, FDA notices, SEC filings and public media announcements, which they claim show that they "expressly advised" laboratories of the defects in their Advantage Kits in 2005. *See e.g.*, Affidavit of Seth R. Goldman.

However, Defendants' reliance upon documents outside the pleadings is inappropriate

may bring an action for unjust enrichment in California even if they did not pay money directly to Defendants or even if they did not suffer a loss at all because the focus of an unjust enrichment claim is on defendants' wrongful conduct).

²² The statute of limitations for a RICO claim is four years and it begins to run from when Plaintiff discovered or should have discovered the RICO injury. *In Re Merrill Lynch Ltd. Partnerships Lit.*, 154 F.3d 56, 58 (2d Cir. 1998); *State Farm Mutual Automobile Ins. Co., v. Grafman*, 655 F.Supp.2d 212 (E.D.N.Y. 2009). "The limitations period does not begin to run until [Plaintiffs] have actual or inquiry notice of the injury." *Allstate Ins. Co. v. Valley Physical Medicine & Rehabilitation, P.C.*, 475 F.Supp.2d 213, 223 (E.D.N.Y. 2007)(quoting *Bankers Trust Co. v. Rhodes*, 859 F.2d 1096, 1103 (2d Cir. 1988)), vacated on other grounds by *Allstate Ins. Co. v. Valley Physical Medicine & Rehabilitation, P.C.*, 555 F.Supp.2d 335 (E.D.N.Y. 2008). Plaintiffs' state and common law claims are subject to various statutes of limitations but generally do not begin to run until discovery of the injury and/or are subject to equitable tolling. *See e.g. Lesoon v. Met. Life Ins. Co.*, 898 A.2d 620, 627 (Pa. Sup. 2006)(citations omitted); *Kominsky v. C.B. Planning Services Corp.*, 2010 WL 3516808 (N.J.Super.A.D.,2010); *Kotlyarsky v. N.Y. Post*, 757 N.Y.S.2d 703, 707-708 (N.Y. Sup. 2003); *Grisham v. Philip Morris U.S.A., Inc.*, 151 P.3d 1151, 1157 n.7 (Cal.2007); *Wiltshire v. A. J. Robins Co., Inc.*, 88 A.D.2d 1097 (4th Dept. 1982).

because they are asking the Court to consider the contents of a few hand-picked documents to prove the truth of a matter at issue. While, “on a motion to dismiss, a court may consider ‘documents attached to the complaint as an exhibit or incorporated by reference, . . . matters of which judicial notice may be taken, or . . . documents either in plaintiffs’ possession or of which plaintiffs had knowledge and relied on,” *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002), said documents can only be considered in regard to “‘what’ they contain, ‘not to prove the truth’ of their contents.” *Roth v. Jennings*, 489 F.3d 499, 511 (2d Cir. 2007).²³

Here, Defendants ask the Court to determine as a matter of fact that they did not deceptively, fraudulently and/or otherwise unlawfully conceal material information regarding the accuracy and reliability of their Kits from the public after 2005.²⁴ However, this issue is disputed by Plaintiffs who assert that Defendants’ concealed such information from Plaintiffs, the Class and the public until April 15, 2009. Thus, Defendants’ use of these documents to prove the truth of a matter in dispute was inappropriate under *Chambers* and *Roth*. Thus, the Court should exclude these documents and disregard them in deciding Defendants’ motion.²⁵

In any event, the evidence is still clear that Plaintiffs’ were not placed on inquiry notice of their injuries until April 15, 2009, the date that Defendants’ deceptive, fraudulent and/or

²³ “[A] ruling on a motion for dismissal pursuant to Rule 12(b)(6) is not an occasion for the court to make findings of fact.” *Roth*, 489 F.3d 509 (citations omitted). The Court cannot look to documents outside the pleadings and decide factual issues at this stage of the case. *Chambers*, 282 F.3d at 155 (“[W]hen a district court considers certain extra-pleading materials and excludes others, it risks depriving the parties of a fair adjudication of the claims by examining an incomplete record.”)

²⁴ Defendants prematurely seek to have the Court decide two factual issues: (1) that these documents did in fact “expressly advise[]” the Plaintiffs that all Kits were defective; and (2) that the notices were sent to the “members of the putative plaintiff class” even though the notices were allegedly only sent to “laboratories” and not to third party payors who also make up the putative class. (Def. Br. at 12). Plaintiffs contest both of these factual issues.

²⁵ The Court has the option of converting Defendants’ motion to one for summary judgment if it chooses to rely upon the documents submitted by Defendants. *Chambers*, 282 F.3d at 154. However, if the Court chooses this option, it must “give the parties an opportunity to conduct appropriate discovery and submit the additional supporting material contemplated by Rule 56. *Id.*

otherwise unlawful behavior was first publicized. Before that date, Plaintiffs had assumed that they had purchased, reimbursed and/or otherwise paid for Kits that had provided reliable and accurate results. There was nothing in the public domain to indicate otherwise.

Indeed, Defendants' own documents support Plaintiffs' position that they could not have discovered that they suffered an economic injury until April 15, 2009 and show Defendants' efforts to conceal the defects in the defective Kits from Plaintiffs, the Class and the public.

To illustrate, Defendants have submitted three product withdrawal notices and one product notification notice of various dates in 2005 (Def. Exh. 1) which purportedly "expressly advised" the laboratories that the kits did not perform as represented. (Def. Br. at 12.) Yet, these notices disclosed far less. The three product withdrawal notices are limited to three lot numbers regarding only two of the allegedly defective Kits (*i.e.*, the iPTH Kits and the Bio-Intact PTH Kits) and the product notification notice is limited to six lot numbers of the iPTH Kits. Thus, Defendants' argument that these four notices, relating to only nine production lots of defective Kits, put Plaintiffs and the Class on notice that a problem existed with all Kits is disingenuous.²⁶

Moreover, by limiting the notices' scope to only certain lot numbers, Defendants further misled Plaintiff, the Class and the public into believing that the problems with Defendants' Kits were only limited to a very small inventory. Indeed, even when Defendants finally notified the public of their hold on all of their Kits (without providing a reason for the hold), they indicated that the problem was being looked into and would be corrected shortly, thus implying that the defects in the Kits were not substantial.²⁷ Defendants never conveyed to the ultimate reader that

²⁶ Similarly, the FDA's recall notices (Def. Exh. 3) did not provide Plaintiffs and the Class with any notice that there was an overall problem with the accuracy and reliability of Defendants' defective Kits as these notices only applied to limited lot numbers, not the entire product line of defective Kits (*compare*, ¶¶ 7, 45, 52-55, 57 alleging all kits, not just certain lot numbers, were fundamentally defective).

²⁷ See Def. Exh. 1, June 16, 2005 Notice ("This is to advise you of a new quality initiative at Nichols Institute Diagnostics (NID) and an accompanying hold on all products at NID...In the short term, this will mean delays in

they were experiencing problems with the reliability and accuracy of all of their Kits so as to provide notice of a potential problem with all of Defendants' Kits. Thus, far from showing that the Defendants "expressly advised" the Plaintiffs of the defect in all the test kits and hid nothing (Def. Br. at 12), these documents actually show that the Defendants concealed the fact that all of their Kits had a fundamental flaw by stating that *some kits may have a problem, but the problem is limited and short-term*.²⁸

Defendants' reliance upon Quest's SEC filings and media reports regarding government investigations (Def. Br. at 13-14), is unavailing. The information contained within these filings and reports is vague and ambiguous²⁹ and is devoid of the requisite information to put Plaintiff and the Class on notice of Defendants' unlawful conduct. *See LaSalle v. Medco Research, Inc.*, 54 F.3d 443, 445-446 (7th Cir. 1995)(finding public action in regulated markets were not indications of fraud, and were not enough to put plaintiff on notice of unlawful conduct); *see also In Re Schering-Plough Corp. Intron*, 2009 WL 2043604 at *22 (D.N.J. 2009)("taking the allegations in the Complaint as true, it is not at all clear that the FDA warning letter, public filings and newspaper articles reporting the Government's investigation of [Defendant's alleged misconduct] provided warnings sufficient to put Plaintiffs on notice of their purported RICO claims...").

obtaining products, because they will not be available until they go through this additional quality review process...It will be necessary to carefully consider whether to wait for the release of our products or to seek alternative solutions for your testing needs. (June 16, 2005 notice at ¶¶ 1-5).

²⁸ Moreover, not in any of these notices do Defendants reveal that they have been aware of the "short-term problems" with their Advantage Kits for quite some time (*i.e.*, five years). Rather, they imply that Defendants' recently discovered the limited defects and were working to correct them.

²⁹ Indeed, the February 28, 2006 SEC filing only notified investors that Quest had "recorded a \$16 million charge to write-off certain assets in connection with a product hold at NID." As to the 2004, 2005 and 2006 SEC filings and media reports, all these documents contained was boiler-plate language that the Defendants may be the subject of adverse action at some point by the federal government for something that they may or may not have done, without providing any further details about exactly what it was that the government was investigating or potential charging. Moreover, any reference to *qui tam* actions within the SEC filings was so broad that it covered every *qui tam* action filed against them, not just the Civil Action discussed herein.

In all events, Plaintiffs' claims should survive Defendants motion for dismissal because the statutes of limitations on Plaintiffs' claims were tolled until April 15, 2009. The "statute of limitations may be tolled as necessary to avoid inequitable circumstances." *Valley Physical Med. & Rehab., P.C.*, 475 F.Supp.2d at 232. Thus, "[e]quitable tolling applies as a matter of fairness where a party had been prevented in some extraordinary way from exercising his rights." *Id.* In the Second Circuit, "equitable tolling requires that a plaintiff establish 'both that there was 'fraudulent concealment' of the violation and the plaintiff exercised 'due diligence' to discover the claim.'" *Id.*

All inferences support Plaintiffs' assertion that Defendants' fraudulently concealed the defects in their Kits until April 15, 2009. Indeed, Defendants' own exhibits reference their fraudulent conduct, *see supra*. Even the FDA notices and media reports show that Defendants had concealed this information. Had the FDA and media been informed of the inaccuracy and unreliability of Defendants' Kits prior to April 15, 2009, they would have reported these defects to the public earlier than April 15, 2009.³⁰

Plaintiffs used due diligence when they first were put on notice of their injuries and commenced this action and all claims within one year of the news reports disclosed on April 15, 2009 that the Kits were defective. Thus, the Plaintiffs claims are subject to equitable tolling.

Lastly, the application of the discovery rule and the equitable tolling doctrine is a question of fact – particularly, here, where a defendant's scheme is "fact-sensitive" and premised on secrecy – and best left to be decided by a jury or the Court at a later date after discovery is

³⁰ Indeed, any random search of the internet today regarding Defendants' deceptive, fraudulent and/or otherwise unlawful conduct reveals that in April 2009, when their misconduct was made public for the first time, many news organizations described in detail, as best they could with the information provided, the specific defects being alleged regarding the kits. Had this information been available to the media prior to April 2009, it would have been included within the media articles submitted by Defendants. Compare *Reuters News*, 10/28/2004 (Quest Ex.5) to *Reuters News*, 04/15/2009, annexed hereto as Ex. 4 to the Declaration of Virginia E. Anello.

completed. *Grafman*, 655 F.Supp.2d at 226 (denying statute of limitations defense brought on a motion to dismiss; because of the fact-sensitive nature of the discovery rule and the equitable tolling doctrine); *see also Valley Physical Med. & Rehab., P.C.*, 475 F.Supp.2d at 232 (same); *see also In re Schering-Plough Corp*, 2009 WL 2043604 *22-23 (same).

Accordingly, for the reasons set forth above, Defendants' motion to dismiss Plaintiffs' claims based upon expiration of the applicable statutes of limitations should be denied.

G. PLAINTIFFS COULD PLEAD ADDITIONAL DETAILS IN THE COMPLAINT TO SUPPORT THEIR CLAIMS SHOULD THE COURT SO REQUIRE

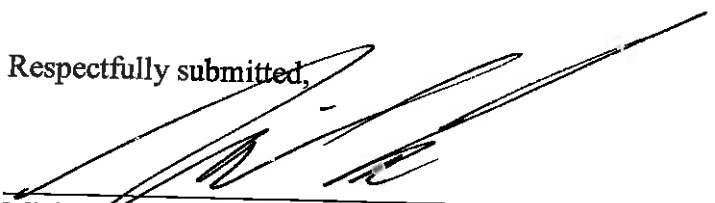
Rule 15(a) provides a party with the right to seek leave to amend their pleading and "[t]he court should freely give leave when justice so requires." Motions for leave to amend should be denied only for reasons such as undue delay, bad faith, futility of the amendment or prejudice to the other party. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *Aetna Cas. & Sur. Co. v. Aniero Concrete Co.*, 404 F.3d 566 (2d Cir. 2005); *Alexandre v. Town of Hempstead*, ___ F.Supp.2d ___, 2011 Westlaw 2181461 at *4-5 (E.D.N.Y. 2011) (holding that leave to amend was proper in light of "the permissive standard applicable to a motion to amend"). Here, amendment would not be futile, given that the Court had asked the parties to commence discovery on the very issues Defendants argue are grounds for dismissal. Accordingly, in the event that this Court decides dismissal of Plaintiffs' claims, in whole or in part, against either Defendant may be warranted, Plaintiffs respectfully request leave to file an amended complaint.

IV. CONCLUSION

WHEREFORE, Plaintiffs respectfully request that the Court (1) deny Defendants' motion to strike in its entirety; (2) deny Defendant's motion to dismiss in its entirety; (3) in the alternative, grant Plaintiffs' request for leave to amend the Complaint; and (4) grant such other and further relief as is just and proper under the circumstances.

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